BRAEBON
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MAY - 1 2003

K031202

510(K) Summary

BRAEBON Medical Corporation MEDI*Palm*–20™

March 20, 2003

The following safety and effectiveness summary has been prepared according to the requirement for 510(k) summaries specified in 21 CFR 807.92c.

1.0 Manufacturer Name

BRAEBON Medical Corporation
120 Walgreen Drive
Suite 1, RR#3
Carp, Ontario
Canada, K0A 1L0

2.0 Proprietary Name of Device

MEDIPalm–20™

3.0 Common Name of Device

Electroencephlograh/polysomnograph

4.0 Device Classification

Devices of this type have been classified as class II by the Neurology Devices Panel. Devices of this classification have a classification code of GWQ, Electroencephalograph (21 CFR 882.1400).

5.0 Intended Use

The BRAEBON Medical Corporation MEDI*Palm*–20™ is intended for use in collecting, recording and displaying physiological data from FDA-cleared sensors during sleep disorder studies in both a clinical and home environment and for transmitting this data to an electrically isolated FDA-cleared polysomnographic analysis station for analysis.

The target population of the MEDI*Palm*–20™ is all children and adult patients who are screened during sleep disorder studies. The majority of the screenings occur at a sleep laboratory but may occur at the patient's house through the use of the MEDI*Palm*–20™.

The MEDI*Palm*–20™ is intended to be used only by or on the order of a physician.

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6.0 Device Description

The MEDI*Palm*–20™ is a hand-held recording device capable of acquiring and storing physiological signals from FDA-cleared sensors and transmitting the physiological data to a computer through the Universal Serial Bus (USB) port.

The MEDI*Palm*–20™ records up to 16 channels of physiological signals: any combination of eight differential analog channels of electroencephalogram (EEG), electrooculogram (EOG), electromyogram (EMG), and electrocardiogram (EKG) signals; as well as chest effort; abdominal effort; airflow pressure; snoring; body position; arterial oxygen saturation (SaO2); pulse rate; and SaO2 probe status. The signals can be viewed in real time on a built-in LCD or on a remote computer. The data can be downloaded after collection for analysis on any FDA-cleared polysomnographic analysis station capable of reading European Data Formatted files.

The MEDIPalm–20™ is powered by either two standard AA batteries, a Medical Grade IEC 60601-1 compliant AC/DC power supply, or an electrically isolated computer that uses an IEC 60601-1 compliant isolation transformer and connects to the MEDIPalm–20™ via the MEDI*Palm* USB data and power cable. To protect the patient when the MEDI*Palm*–20™ is used with a computer, the computer and all its peripherals must be connected to an IEC 60601-1 compliant isolation transformer. The sensors connect to the patient and the MEDI*Palm*–20™. The MEDI*Palm*–20™ does not contain any patient contacting materials.

7.0 Predicate Device Equivalence

We are claiming substantial equivalence to the following devices:

Airsep Corp.	Monet	K001013
EB Neuro. S.P.A.	Sandman Digital	K003154
Nellcor Puritan Bennett	Suzanne	K990565
Nonin Medical, Inc.	PalmSAT, Model 2500 Pulse Oximeter with finger probes	K002690
BRAEBON Medical Corporation	Ultima Smartbelt	K001743
BRAEBON Medical Corporation	Ultima Airflow Pressure Sensor	K984431

8.0 Similarities and Differences Between Subject and Predicate Devices

Intended Use	No difference
Indications Statement	No difference
Method of Connection to Patient	No difference
Power Source	No significant difference. The MEDI*Palm*–20™, like the predicate devices, is powered by batteries or a Medical Grade IEC 60601-1 compliant AC/DC power supply. The MEDI*Palm*–20™ can also be powered using the MEDI*Palm* Universal Serial Bus (USB) data cable. When using the MEDI*Palm*–20™ with the computer, the computer and all its peripherals must be connected to an IEC 60601-1 compliant isolation transformer to protect the patient.
Safety Characteristics	No difference.
Reuse and Hygiene Characteristics	No difference.
Design	No difference. The MEDI*Palm*–20™ incorporates the headbox, respiratory effort sensor, airflow pressure sensor, and pulse oximeter into one palm-sized case rather than multiple cases.
Performance Data Conclusions	No difference.

9.0 Performance Testing

Functional testing was performed to confirm that MEDI*Palm*–20™ is capable of meeting its stated performance specifications and that the device output is readable. MEDI*Palm*–20™ passed all tests.

All software testing was performed in accordance with the May 29, 1998 "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" published by the Office of Device Evaluation. The MEDI*Palm*–20™ passed all tests.

All software verification and validation testing was performed in accordance with the January 11, 2002 "General Principles of Software Validation; Final Guidance for Industry and FDA Staff." The MEDI*Palm*–20™ passed all tests.

All environmental and electrical safety testing was performed in accordance with the November 03, 1997 "Electroencephalograph Devices Guidance for 510(k) Content." The MEDI*Palm*–20™ passed all tests.

No clinical studies were required to support a substantial equivalence determination. The MEDIPalm–20™ was connected to a healthy person and was run to verify that readable, appropriate signals were being recorded. Simulation tests comparing the MEDIPalm–20™ and the Sandman Digital were also performed to gather comparative performance data. The performance of the BRAEBON Medical Corporation MEDIPalm–20™ (subject device) was identical to that of Sandman Digital Recording System (predicate device).

10.0 Conclusions

We conclude that MEDI*Palm*–20™ is equivalent in safety and performance to the legally marketed predicate devices. The MEDI*Palm*–20™ meets its stated performance specifications and the criteria outlined in the Reviewers Guidance publication specified above, and the MEDI*Palm*–20™ will operate safely in the intended environment and fulfill its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2003

Braebon Medical Corporation
c/o Mr. Neil E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K031202
Trade/Device Name: MEDIPalm-20™
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: April 16, 2003
Received: April 16, 2003

Dear Mr. Devine :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

For Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510 (k) Number K 031202 ~~(To be assigned)~~

Device Name:	MEDI*Palm*–20™
Indications for Use:	The MEDI*Palm*–20™ is a portable data recorder used to collect physiological signals for transfer to an FDA-cleared polysomnographic analysis station capable of reading European Data Format (.edf) files.
Target Population:	Children and adult patients who are screened during sleep disorder studies
Environment of Use:	The majority of the screenings occur at a sleep laboratory, hospital or at the patient's home.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031202

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)